Example Format for an Integrated Exposure Assessment Relevant to Children's Exposures

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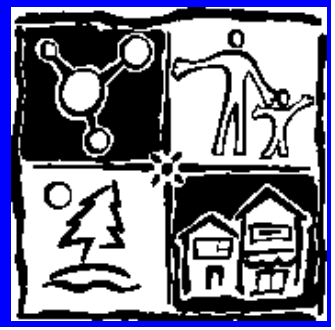


Consistency: Use of the Exposure Summaries

- Use of a consistent format is important to help characterize the completeness and quality of the exposure assessment results in a very transparent manner
- Consistent data entry into a standard template will allow both assessors/preparers and readers to understand the exposure assessment information quickly and correctly

Completeness and Data Quality: Entering Data Into the Summaries

- Use of the summaries will help characterize the completeness and quality of the exposure assessment in a consistent manner
- Completeness will be demonstrated by inclusion of all relevant summaries
- Data quality and transparency will be demonstrated through descriptive entries into the summaries

Chemical C Characteristics

- High volume chemical
- Potential for exposure to children through
  - manufacturing releases
  - parental occupational exposure
  - residential exposures
  - food and water

Overview of Summaries

- Summary 1: General Information
- Summary 2: Releases and Exposure
- Summary 3: Monitoring Evaluations
- Summary 4: Modeling Evaluations

- Following the General Information Summary, Summaries 2, 3, and 4 are nested within each specifically numbered activity
- e.g., Activity #1: Manufacturing, Activity #2: Processing, Activity #3: Use 1 – Indoor Residential Crack and Crevice Treatment, etc.
- Each Activity can have multiple evaluations (a, b, c, etc.)

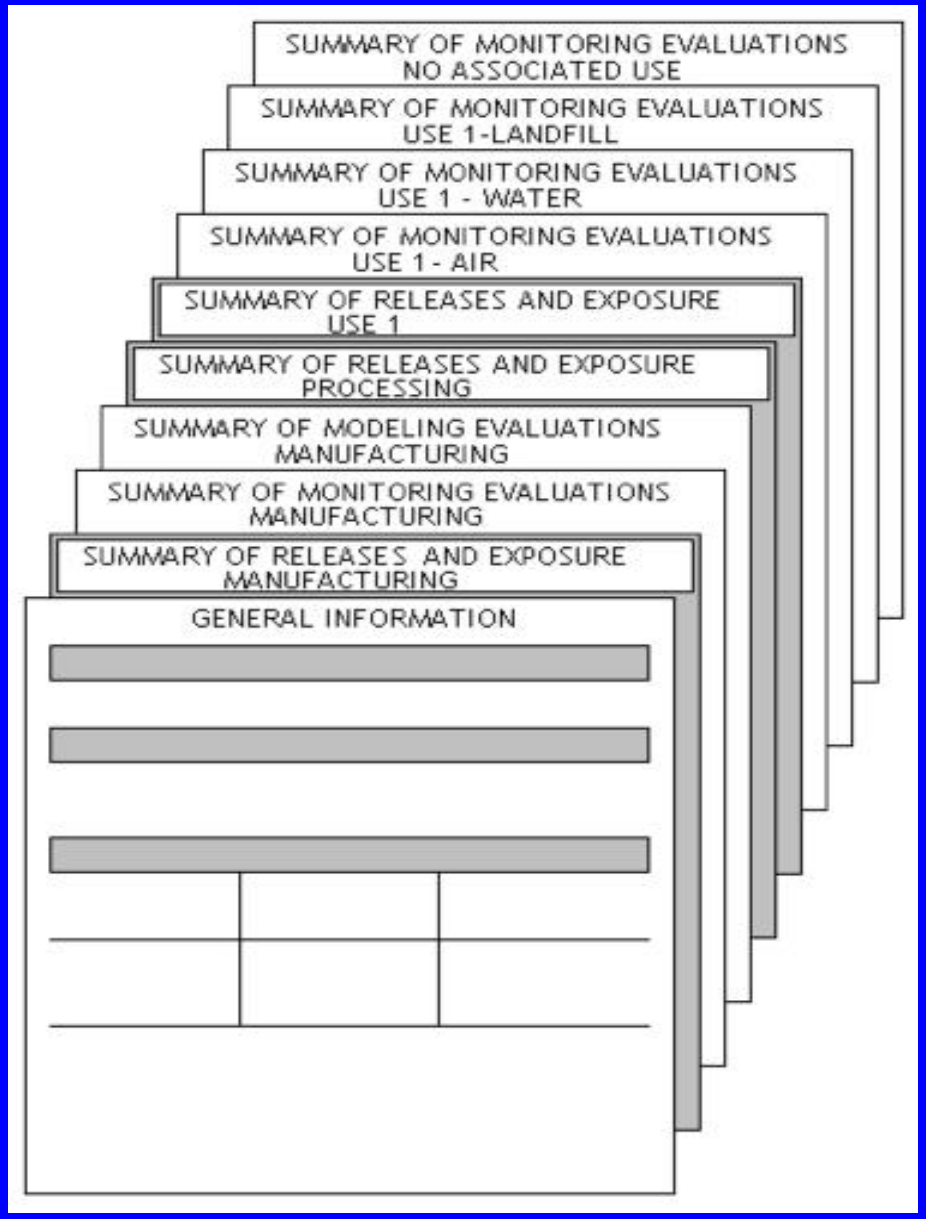


Figure 2. Example of Exposure Formats in a Complete Submission

- **Nested format of summaries**
- **Individual monitoring and modeling evaluations follow the exposure and release summary for each activity**

Summary 1: General Information

- Originator
- Physical characteristics
- Volume and end use
- Executive Summary
  - Narrative description
  - Summary table of monitoring and modeling evaluations
  - Summary table of exposure results

Overview: General Information

EXAMPLE - GENERAL INFORMATION			
1.	**Originator**		
a.	Originator Name	Inert Manufacturers, Inc.	
b.	Technical Contact	Dr. Edgar Bee 226 Hive St. Honeywell, CA 00000 Phone: (000) 111-0000 Fax: (000) 111-0001 ebee@hive.com	
c.	Submittal Date	06/23/01	
2.	**Chemical ID**		
a.	Name	Chemical C	
b.	Synonyms	Chem-X, diphenyl X	
c.	CAS #	1111-00-1	
d.	Physical/Chemical Properties	Physical Form (neat) Molecular Weight = 220 Log octanol-water partition coefficient (Log Kow) = 3.4 Vapor Pressure (25EC) = 5.0E-4 mmHg Water Solubility (25EC) = 120 mg/L Melting Point = -15EC Boiling point = 120°C HLC (25EC) = 2.3E-6 atm m^3/mol Density (25EC) = 1.6 g/mL	Photolysis: ½ life = 23 days Hydrolysis: ½ life = 10 days Biodegradation: ½ life = 15 months (water) Transport/distribution = Soil - 80% Water - 5% Sediment - 10% Air - 5%

Summary 1: General Information

- General Information
  - 1,300,000 pounds/year, low VP, assessment represents 75% of U.S. volume
- Summary of Releases and Exposure
  - Manufacturing, processing, indoor residential use, nonpoint sources, miscellaneous uses
- Summary of Monitoring Evaluations
  - Exposure of infants through breast milk, worker inhalation exposure, postapplication inhalation exposure
- Summary of Modeling Evaluations
  - General population exposure (fugitive emissions), dermal and hand-to-mouth exposure, aggregate children's exposure

Volume and End Use Summary

- Total volume of assessment broken out by manufacturing, processing, and use
- Completeness of end use information is important

3.	**Volume and End Use**					
a.	Volume	Units	Total US		Assessed	
		☒ pounds ☐ kilograms	Volume/year	percent	Volume/year	percent
		Manufactured	1,300,000	100	1,000,000	75
		Imported	0	0	0	0
		Total	1,300,000	100	1,000,000	75
b.	Uses	Indoor Insecticide	1,300,000	100	1,300,000	100
		Other	0	0	0	0
		Export	0	0	0	0

Summary of Data Included in Assessment

- Tabular version of exposure summaries
- Shows releases and exposure by individual use, including monitoring evaluations and modeling evaluations
- Actual exposure calculations shown in results table and individual summaries

4. Executive Summary (Continued)

e. Contents

Summary of Releases and Exposure	Summary of Monitoring Evaluations	Summary of Modeling Evaluations
1. Manufacturing	**a.** Exposure of infants of working mothers	**b.** General population exposure from fugitive air emissions
2. Processing	**c.** Worker inhalation exposure	None
3. Use 1 - Indoor Residential Crack and Crevice Treatment	**d.** Adult handler exposures (dermal and inhalation)	**f.** Dermal and hand-to-mouth post-application exposure
	e. Postapplication inhalation exposure	
4. None (no associated use or release information available)	**g.** Ingestion of groundwater	None
5. None (various uses)	None	**h.** Aggregate children's exposure

Summary of Exposure Results

- Tabular version of exposure results
- Monitoring, modeling,and exposure calculations results shown

4. Executive Summary (Continued)

f. Table of Exposure Results **Scenario**	**Acute Exposures APDR (mg/kg/day)**	**Chronic Exposures ADD (mg/kg/day)**	**Population**
breast feeding infants of working mothers	0.003 - 0.025	0.003 - 0.025	infants
air release to environment during manufacturing	1.36×10^{-7} (maximum dose)		local population around manufacturing facility
inhalation of indoor air at processing facility	$< 7.0 \times 10^{-6}$	$< 5.0 \times 10^{-6}$	workers in processing facility
inhalation of indoor residues during application	7.1×10^{-7} to 1.4×10^{-6}	2.4×10^{-8} to 4.7×10^{-8}	adult applicators
dermal contact with indoor residues during application	0.009 to 0.017	2.8×10^{-4} to 5.6×10^{-4}	adult applicators
inhalation of indoor residues post-application	$<3.0 \times 10^{-6}$	$<3.0 \times 10^{-6}$	child
dermal contact with indoor residues post-application	0.4	0.4	child
non-dietary ingestion of indoor residues post-application	0.13	0.13	child
ingestion of groundwater	1.7×10^{-5}	6.7×10^{-6}	child
aggregate exposure	0.53	0.46	child

Overview of Activities and Evaluations

- Activity #1: Manufacturing
  - Releases and exposure summary
  - Evaluation a: Infants of working mothers (monitoring)
  - Evaluation b: Fugitive emissions to general population (modeling)
- Activity #2: Processing
  - Releases and exposure summary
  - Evaluation c: Worker inhalation (monitoring)
- Activity #3: Use 1–Indoor Residential Crack/Crevice Treatment
  - Releases and exposure summary
  - Evaluation d: Dermal/inhalation: adult handlers (monitoring)
  - Evaluation e: Postapplication Inhalation (monitoring)
  - Evaluation f: Dermal and hand-to-mouth post-application exposure (modeling)
- Activity #4: Unassociated with Specific Uses
  - Releases and exposure summary
  - Evaluation g: Ingestion of groundwater (monitoring)
- Activity #5: Various Uses
  - Releases and exposure summary
  - Evaluation h: Aggregate children's exposure (modeling)

How-To: Completion of Specific Summaries

- Summary 1: General Information
- Summary 2: Releases and Exposure
  - Activity #2, Processing
- Summary 3: Monitoring Evaluations
  - Activity #1, Manufacturing
    - Evaluation a: Exposure of Infants of Working Mothers
- Summary 4: Modeling Evaluation
  - Activity #3, Use 1 – Indoor Residential Crack and Crevice Treatment,
    - Evaluation f: Dermal and hand-to-mouth post-application exposure

Summary 2: Summary of Releases and Exposure

- Activity number and description (i.e., Activity #2, Processing)
- Physical form, concentration, and site information
- Process description
- Release information
- Engineering controls, PPE, and Regulatory Requirements

Summary 2: Summary of Releases and Exposure Activity #2, Processing

Activity #: 2 Description: Processing

1. Activity and Associated Volume

Activity type	Activity Description/Function	Volume
☐ Manufacturing		
☒ Processing/Formulation	Chemical C is purchased from Inert Manufacturers, Inc. and delivered on trucks to Pesticide Formulators, Inc. where it is unloaded via pump to a mixing vessel where it is processed into the formulated product (Pest-X) at a concentration of 50% pesticide and 50% liquid inert ingredients (Chemical C).	10,000 lb/yr
☐ Use		

2. Physical Form and Concentration

As Received:						
Form:	G Dry Powder	G Pellets or Large Crystals	G Water or Solvent Wet Solid	G Gas or Vapor	☒ Liquid	G Other
Concentration:					100%	
As it leaves the site:						
Form:	G Dry Powder	G Pellets or Large Crystals	G Water or Solvent Wet Solid	G Gas or Vapor	☒ Liquid	G Other
Concentration:					50%	

Description: Chemical C is formulated into a 50% emulsifiable concentrate to be diluted 1:10 in water by the user.

3. Site Information

a. Site Type

☐ Residential

☐ Commercial/Institutional

☒ Industrial

b. Number of Sites	Total US Sites (indicate if estimate)	Sites addressed in this assessment
	10	1

c. Site Locations: The processing facility is located at 0 Fairfax Street, New City, NJ.

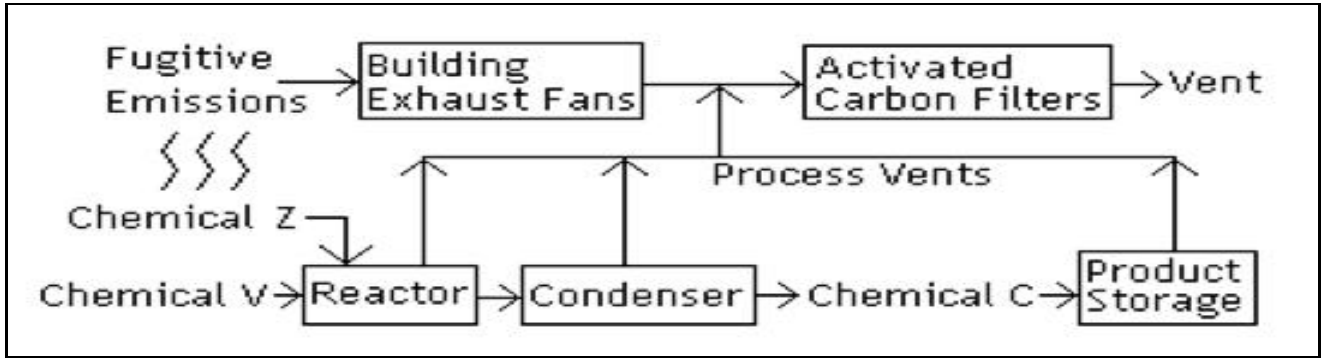
- Volume by activity
- Physical form and concentration by activity
- Site type and location information
- Important data for exposure estimations and calculations by site

Summary 2: Summary of Releases and Exposure Activity #2, Processing (continued)

- Process description supports transparency of assessment and helps the reader understand releases and exposure

4. Process Description

Chemical C is produced in a gaseous state by reacting in a reactor at temperatures between 60E C and 150E C. The gaseous Chemical C is then fed into a condenser. Chemical C is converted to a liquid state by the condenser. The liquid product is then transferred to a storage tank. The material is later transferred into trucks for transporting to customer sites. The process runs continuously producing 4,000 lbs/day over 250 days/year operation for a total annual production of 1,000,000 pounds. Fugitive losses and emissions from all process equipment are captured via the exhaust fans and passed through activated carbon filters (@ 95% efficiency) before venting to the atmosphere. The basic flow of the process can be presented as follows: Chemical V –> Reactor –> Condenser –> Chemical C –> Product Storage. A diagram of the manufacturing process is presented below.



Manufacturing of Chemical C

Summary 2: Summary of Releases and Exposure Activity #2, Processing (continued)

5. Release Information (Continued)

Specify units: ☐ lbs Or **9** kgs		Estimated Total Annual Releases	# days/year release occurs
A.	On-site Air Release		
	Fugitive	900	365
	Stack	100	365
	Basis for Estimate (attach additional calculations as desired): Based on published emission factors for similar process, the manufacturing of Chemical Cy which is analogous in structure to Chemical C, and is also manufactured using identical unit operations.		
B.	Water Releases from Site		
	Water Releases	NA	
	Receiving water name:	NPDES #:	
	Basis for Estimate (attach additional calculations as desired):		
C.	On-Site Land Releases		
	Landfill	NA	
	Land Treatment/ Land Amendment	NA	
	Surface Impoundment	NA	
	Underground Injection	NA	
	Other (specify)	NA	
	Basis for Estimate (attach additional calculations as desired):		

- Release data by type: fill-in format facilitates completion of form
  - Air
  - Water
  - On-site land
  - Off-site land
  - POTW
  - Other off-site location

Summary 2: Summary of Releases and Exposure Activity #2, Processing (continued)

- Description of engineering controls, PPE requirements, occupational and environmental exposure limits (if applicable)

6. Engineering Controls and Personal Protective Equipment

a. Engineering Controls - A closed mixing and closed mechanized packaging system are used during processing.
b. Personal Protective Equipment - PPE is not required in this plant because of the use of a closed system.
c. Regulatory Requirements - Workers are covered by OSHA requirements.

Occupational Standards:
TLV: 100 ppm
PEL: 10 ppm
STEL: 50 ppm

Federal Environmental Standards:
TRI: Yes
HAP: Yes
CWA Priority Pollutant: No
RCRA U&P Waste: UUUU
Others: _____

SWDA contaminant: No
CERCLA reportable quantity: 1 lb

Summary 2: Summary of Releases and Exposure Activity #2, Processing (continued)

7. Summary of Exposure Results

Potential inhalation exposures were found to be very low (i.e., below the limit of detection of 0.05 μg/m³) based on personal monitoring of workers in the processing plant. Based on the limit of detection, an assumed inhalation rate of 1.2 m³/hr, and an exposure duration of 8 hrs/day, exposure was estimated to be <0.007 μg/kg/day. Dermal exposure was not monitored.

Occupational, General Population, and Consumer Exposure Summary:

(1) Activity	(2) Physical Form		(3) Number of Persons Exposed	(4) Maximum Duration	
	(a) Form	(b) Conc.		Hours/day	Days/year
a. Inhalation of Indoor Air	gas	<0.05 μg/m³	15 (estimated number of workers in processing facility)	8	250

8. References

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9. Contents

Summary of Monitoring Evaluations Associated with this Release	Summary of Modeling Evaluations Associated with this Release
Monitoring data for air and water releases from the processing facility are currently being collected. Thus, general population exposures are not assessed.	
c. Worker inhalation exposure	-----

- **Summary table of exposure evaluations included for this activity (both monitoring and modeling)**
- **References**
- **Table of contents of all evaluations (by type) for this activity**

Summary 3: Summary of Monitoring Evaluations
Activity #1, Manufacturing
Evaluation a: **Exposures of Infants of Working Mothers**

Activity #: _1_ Description: Manufacturing
Evaluation: _a_ Description: Exposure of infants of working mothers

2. Date of Monitoring Study

01/01/01

3. Monitoring Study Objective

The objective of the study was to estimate the concentration of Chemical C in the breast milk of nursing mothers that were exposed to Chemical C. The strategy was to examine different scenarios that would cover most of the occupational exposures associated with Chemical C.

4. Exposure Assessment Objective

The objective of the assessment was to estimate the potential exposure to infants associated with the consumption of breast milk that was contaminated with Chemical C.

5. Sampling Methods

Single breast milk samples were collected from each of 4 women who worked at our facility that manufactures Chemical C. Samples of approximately 50 mL were collected. Samples were collected, stored, and shipped to the laboratory at 4EC. Only minimal physiological data were collected for the 4 subjects. Sample chain of custody forms were used to track samples.

6. Analytical Chemistry Methods

SW 846, Method XXXX was used to analyze the samples. (U.S., EPA, 1986). Analyses were performed by ABC Laboratories in Main Town, PA.

- **Study Objective and Date**
- **Assessment Objective**
- **Sampling Methods**
- **Analytical Chemistry Methods**

Summary 3: Summary of Monitoring Evaluations Activity #1, Manufacturing Evaluation a: **Exposures of Infants of Working Mothers** (continued)

7. QA/QC Procedures

The data collected during the monitoring study were screened for use in the exposure assessments. Quality assurance objectives were outlined in a Quality Assurance Plan that was prepared as part of the study and before sampling began (University of Important Study, 2001). The Plan outlined the QA/QC procedures that were followed by the laboratory. To check the validity of the results from the lab, a single blind duplicate was submitted. Negative (i.e., blank) control samples were also analyzed. All of the quality assurance objectives that were set were met. All quality control procedures have been employed and documented.

8. Results

a. Monitoring Results - Breast milk concentrations ranged from 0.03 to 0.26 mg/L Chemical C with a mean of 0.11 mg/L over 4 samples.

b. Exposure Estimates - Chemical C intake for infants was estimated to range from 0.003 to 0.025 mg/kg/day. Exposure to infants was estimated based on the assumptions of a breast milk intake of 0.7 L/day and an infant body weight of 7.2 kg. (U.S. EPA, 1989). The Acute Potential Dose Rates (APDRs) were calculated as follows:

APDRs = (Breast Milk Concentration) x (Consumption Rate) / (Body Wt)
0.003 mg/kg/day = (0.03 mg/L) x (0.7 L/day) / (7.2 kg)
0.025 mg/kg/day = (0.26 mg/L) x (0.7 L/day) / (7.2 kg)

Average Daily Doses (ADDs) were the same as APDRs because the same exposure occurs every day over the duration of breast feeding (i.e., 1 year).

9. Uncertainty

Factors such as body weight, race, and proximity of the subjects' residences to the facility were not addressed. These factors could have contributed to or detracted from the effects of Chemical C on the subject. Other potential sources of Chemical C exposure were not evaluated.

10. References

- QA/QC
  - Sufficient Detail
  - Transparency
- Results with ADD calculations
- Uncertainty
- References

Summary 4: Summary of Modeling Evaluations Activity #3, Use 1-Indoor Res. Crack/Crevice Treatment Evaluation f: **Dermal and Hand-to-Mouth Postapplication Exposure**

Activity #: 3 **Description:** Use 1 - Indoor Residential Crack and Crevice Treatment
Evaluation: f **Description:** Dermal and Hand-to-Mouth Postapplication Exposure

2.	**Modeling Study Objective**
The purpose of this modeling exercise was to provide a conservative estimate of dermal and hand-to-mouth exposure based on the application rate and default exposure assumptions for hard surfaces. Exposures were assessed on the day of application (i.e., assumes no dissipation) to provide upper percentile estimates.	
3.	**Model Name, Version Number, Run Date**
SOPs for Residential Exposure Assessment, Sections 8.2.2 and 8.4. U.S. EPA, 2001. Run 4/7/01. This is not a computerized model. It is a document prepared by EPA's Office of Pesticide Programs that provides algorithms and assumptions for various pesticide exposure scenarios.	
4.	**Validation/Peer Review Status of Model**
The SOPs document has been developed and internally reviewed by various EPA offices and the Science Advisory Panel.	
5.	**Availability of Model**
Document available from U.S. EPA.	

- Objective, Methods
  - Sufficient Detail
  - QA/QC
- Model Name, Version Number, Run Date
  - Computerized model or other, i.e., SOP
- Validation/Peer Review Status of Model
  - Internal or external validation
- Availability of Model
  - Open or proprietary format

Summary 4: Summary of Modeling Evaluations Activity #3, Use 1-Indoor Res. Crack/Crevice Treatment Evaluation f: **Dermal and Hand-to-Mouth Postapplication Exposure** (continued)

Key **Model Inputs &Algorithm/Assumptions**:

Variables:

Physical: Body weight, surface area, dermal absorption, etc.
i.e., Dermal:
-Transfer coefficients
-Absorption fraction
-Duration

Behavioral: Activity frequency, duration
i.e., Hand-to-Mouth:
-Hand surface area
-Frequency of event
-Duration

7. Model Algorithm/Assumptions

Absorbed Dermal Acute Potential Dose Rate (APDR) (mg/kg/day) = indoor surface residue (mg/cm^2) x transfer coefficient (cm^2/hr) x absorption fraction x exposure time (hr/day) / body weight (kg).
Indoor Surface Residue = application rate (lbs/ft^2) x fraction of residue retained on surface.
Hand-to-Mouth Acute Potential Dose Rate (APDR) (mg/kg/day) = indoor surface residue (mg/cm^2) x skin surface area (cm^2/event) x frequency of hand-to-mouth events (events/hr) x saliva extraction fraction x exposure time (hrs/day) / body weight (kg).
The assumptions were as follows: 10% of the application rate is available for dislodging, the transfer coefficient is 6,000 cm^2/hr for toddlers, and the exposure time is 4 hours/day. Exposure is assessed on the day of application (i.e., no dissipation). Surface area is assumed to be 20 cm^2/event (hands) for toddlers; frequency is 20 events/hour; saliva extraction factor is 50%. Body weight is assumed to be 15 kg, and absorption is assumed to be 10% for Chemical C. The Dermal Average Daily Dose (ADD) is calculated as the APDR times the exposure frequency of 365 days per year and the exposure duration of 3 years divided by the averaging time of 3 years times 365 days/yr. The Hand-to-Mouth ADD uses an APDR with a hand-to-mouth frequency of 9.5 events/hr and is calculated as the APDR times an exposure frequency of 365 d/yr for 3 years divided by an averaging time of 3 years times 365 days/yr.

Summary 4: Summary of Modeling Evaluations Activity #3, Use 1-Indoor Res. Crack/Crevice Treatment Evaluation f: **Dermal and Hand-to-Mouth Postapplication Exposure** (continued)

8. Description of Exposure Scenario
The scenarios assessed here assume Chemical C is transferred to the skin of a toddler (3-year old child) who comes into contact with areas treated with Pest-X, such as floors and counter tops during play activities. Exposure occurs from dermal uptake and/or hand-to-mouth contact.
9. Results
Based on modeling, postapplication dermal exposure (i.e., APDR and ADD) among 3-year old children was estimated to be 0.4 mg/kg/day, and non-dietary (hand-to-mouth) exposure was 0.13 mg/kg/day (APDR) and 0.063 mg/kg/day (ADD).
10. Uncertainty
Uncertainties occur from assumptions regarding dissipation and transfer of Chemical C. The transfer coefficient is based on data for adults (scaled to children) (Cal EPA, 1996). Also, uncertainties exist related to skin surface area, hand-to-mouth frequency, and absorption factor. The absorption fraction is based on a single study using pigskin to evaluate dermal uptake of Chemical C. According to U.S. EPA (2001), the exposure estimates generated by this method are assumed to represent high-end exposures. Because a combination of central tendency and high-end, conservative inputs were used, the estimates are believed to be upper percentile values.
11. References
U.S. EPA, 2001. Standard Operating Procedures for Residential Exposure Assessment. CAL EPA, 1996. Memorandum regarding transfer coefficients. Pesticide Formulators, 2000. Absorption of Chemical C Through Pig Skin. Draft Report.

- Description of Exposure Scenario
- Results
- Uncertainty
  - Amount of supporting data
  - Statistic of data used (e.g.., mean, 90th percentile) to support model
  - Is model designed for children or adults?
- References

Summary

- The summary forms are completed according to activity, with nested monitoring and modeling data for each activity
- The summaries illustrate the benefits of a consistent format for describing and understanding exposure assessment data
- A consistent format benefits both the assessor and the reader
- Consistency in reporting demonstrates the data quality and transparency of the assessment